

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

Bray v. Ameridose, LLC, et al., No. 1:13-cv-12596;
Collins v. Ameridose, LLC, et al., No. 1:13-cv-12580;
Cox v. Ameridose, LLC, et al., No. 1:13-cv-12918;
Dingess v. Ameridose, LLC, et al., No. 1:13-cv-12490;
Graham v. Ameridose, LLC, et al., No. 1:13-cv-12581;
Hubbard v. Ameridose, LLC, et al., No. 1:13-cv-12922;
Jackson v. Ameridose, LLC, et al., No. 1:13-cv-12923;
Johnson v. Ameridose, LLC, et al., No. 1:13-cv-12915;
Lapiska v. Ameridose, LLC, et al., No. 1:13-cv-12914;
Nealon v. Ameridose, LLC, et al., No. 1:13-cv-12491;
Norris v. Ameridose, LLC, et al., No. 1:13-cv-12682;
Palmer v. Ameridose, LLC, et al., No. 1:13-cv-12688;
Reed v. Ameridose, LLC, et al., No. 1:13-cv-12917;
Savercool v. Ameridose, LLC, et al., No. 1:13-cv-12583;
Willis v. Ameridose, LLC, et al., No. 1:13-cv-12597.

MDL No. 2419

Master Docket No.: 1:13-md-2419 (RWZ)

**Plaintiffs' Steering Committee's Response in Opposition to Specialty Surgery Center
Defendants' Fed. R. Civ. P. 12(b)(6) Motion to Dismiss**

On September 12, 2016 Specialty Surgery Center LLC, Dr. Kenneth Lister, and Kenneth Lister P.C. (the “Specialty Surgery Center Defendants”) filed a Rule 12(b)(6) Motion to Dismiss (Dkt. No. 3086, the “Motion”) seeking to dismiss fifteen cases for an alleged failure to comply with Tenn. Code Ann. § 29-26-122’s certificate of good faith requirements related to healthcare liability actions. The Plaintiffs’ Steering Committee files this Response in Opposition to Specialty Surgery Center Defendants’ Motion to Dismiss.

Procedural Background

On September 12, 2016, the Specialty Surgery Center Defendants filed the present Motion seeking to dismiss 15 of the 24 cases pending against them on procedural technicalities stemming from Tennessee’s Healthcare Liability Act, Tenn. Code Ann. § 29-26-101m *et seq.* (the “THCLA”). These 15 cases fall into three respective categories:

1. Cases that were originally filed without a certificate of good faith but that 1) asserted only claims under Tennessee’s Product Liability Act, Tenn. Code Ann. § 29-28-101, *et seq.* (the “TPLA”), 2) specifically disclaimed liability under the THCLA; and, 3) amended to include the certificate of good faith in December 2014 (these cases include the *Bray*, *Collins*, *Graham*, *Savercool*, and *Willis* cases and will be referred to as the “Branstetter Actions”);
2. Cases that were originally filed without a certificate of good faith and 1) did not specifically disclaim liability under the THCLA; and 2) were amended to include the certificate of good faith in December of 2014 (these cases include the *Palmer* and *Norris* actions and will be referred to as the “Cain Actions”); and
3. Cases that were originally filed without a certificate of good faith 1) and did not specifically disclaim liability under the HCLA; and 2) were amended in December 2014 but did not include a certificate of good faith (these cases include the *Cox*, *Dingess*, *Hubbard*, *Jackson*, *Johnson*, *Lapiska*, *Nealon*, and *Reed* actions and will be referred to as the “Remaining Actions”).

Previously, the Specialty Surgery Center Defendants had sought dismissal of these cases in January 2014.¹ This motion was largely denied by the Court in its order of August 28, 2014.² (the “Motion to Dismiss Order”).

The Specialty Surgery Center Defendants now seek a second bite of the dismissal apple for the above-cases on the basis that a failure to file a certificate of good faith with the *original* complaint proves fatal to plaintiffs’ claims. However, under this Court’s previous rulings, the Branstetter Cases did not have to satisfy the certificate of good faith requirements and the Motion is wholly without merit as to them. With respect to the Cain Actions, the filing of the amended complaint supersedes the original complaint and permits these cases to move forward. With respect to the Remaining Actions, for the reasons articulated below, it is clear under Tennessee law these cases should be granted an extension to file the certificate of good faith in a time to be determined by the Court.³

ARGUMENT

I. The Branstetter Actions Are Not Subject To Dismissal

a. The Court Has Already Ruled On The Issue of Law Applicable To The Branstetter Actions.

This Court has already ruled that filing a pure products liability action without complying with the THCLA is proper and does not warrant dismissal. Specifically, in the Motion to Dismiss Order, this Court asked the following question: “Do the pre-suit notice and good faith certificate requirements of the THCLA apply to plaintiffs’ original complaints alleging only products liability claims?”⁴

¹ Dkt. Nos. 770 and 771.

² Dkt. No. 1360, the “Motion to Dismiss Order”

³ As part of this relief, the PSC is filing contemporaneously a cross motion for extension of time to file certificates of merit under Tenn. Code Ann. § 29-26-122(c)(3).

⁴ Dkt. No. 1360 at P. 16.

In answering this question in the negative the Court held as follows:

The parties offer no case law, and I have uncovered none, addressing these issues with respect to the amended THCLA or to products liability claims specifically. The THCLA's new definitions are broad and can conceivably be interpreted to span a wide variety of claims and theories of liability. However, the historical treatment of other civil claims under the TMMA, the lack of explicit support for defendants' argument that the THCLA is now the sole cause of action against health care providers, and the different showing of proof required for products liability as opposed to claims under the THCLA all suggest that plaintiffs should be permitted to plead products liability claims as separate from health care liability. Like the court in *Parker*, I am loath to require compliance with THCLA requirements for non-THCLA claims, and therefore rule that plaintiffs did not have to give pre-suit notice or file certificates of good faith with original complaints alleging only products liability.⁵

Plaintiffs in the Branstetter Actions alleged only products liability claims in their original complaints. The Court's Motion to Dismiss Order therefore found that the Branstetter Actions are not subject to dismissal for failure to comply with Section 122's certificate of good faith requirement.

In their Motion, the Specialty Surgery Center Defendants act as if the Court's earlier ruling never occurred. They utterly fail to address the fact that this Court has already answered the question as to whether the Branstetter Actions are subject to dismissal for failure to comply with Section 122's certificate of good faith requirements. Moreover, they fail to argue why the Court's holding should be reconsidered now. Indeed, they fail to even argue the exacting standards used for motions for reconsideration,⁶ presumably because no factor in that analysis supports their attempts to re-litigate this issue.

⁵ *Id.* at P. 20.

⁶ *Nw. Bypass Grp. v. U.S. Army Corps of Eng'rs*, 552 F. Supp. 2d 137 (D.N.H. Apr. 22, 2008) (citing *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006) (noting that reconsideration is an extraordinary remedy and should be used sparingly); see also *Oahn Nyugen Chung v. StudentCity.com, Inc.*, Civil Action No. 10-10943-RWZ, 2013 U.S. Dist. LEXIS 18589, at *3-4 (D. Mass. Feb. 12, 2013) (Zobel, J.).

The Court should therefore apply its earlier ruling and deny the Motion as it relates to the Branstetter Actions. Moreover, the Specialty Surgery Center Defendants' failure to address why this Court should reconsider its holding in the Motion to Dismiss Order is also sufficient basis to deny the Motion as to the Branstetter Actions. The Court's analysis should end there. Regardless, and because it is important to understand the interaction between the THCLA and the TPLA, this opposition will re-address some of the issues that form the basis of the Court's holding in the Motion to Dismiss Order.

b. Inconsistent Statutes Create Procedural Catch 22.

Because of certain inconsistencies between the temporal requirements of the Product Liability Act and the Healthcare Liability Act, the Branstetter Actions included product liability claims only in their initial complaints. They expressly disclaimed liability under the THCLA in their initial complaints because those claims were not yet ripe.

Under the TPLA, arguably, Tennessee's one year statutory limitations period begins to run on the date when a plaintiff discovers or reasonably should discover that he or she was injured by an unreasonably dangerous or defective product.⁷ The TPLA does not require any pre-suit notice before litigation is commenced. On the other hand, under the THCLA the statute of limitations expires one year and 120 days after a party discovers an injury related to the provision of health care services and after a patient or their representative provides the healthcare provider with a particular pre-suit notice.⁸ That pre-suit notice must be given at least 60 days before suit is filed. If the plaintiff complies with that 60 day pre-suit notice requirement, then the one year statute of limitations applicable to all personal injury claims is extended by 120 days.⁹

⁷ Tenn. Code Ann. § 29-28-103; and *McCroskey v. Bryant Air Conditioning Co.*, 524 S.W.2d 487 (Tenn.1975).

⁸ See Tenn. Code Ann. § 29-26-116 citing Tenn. Code Ann. § 28-3-104 (imposing one year statute of limitations for claims under the Healthcare Liability Act).

⁹ Tenn. Code Ann. § 29-26-121(c).

Accordingly, one possible consequence of the incongruent temporal requirements applying to product liability claims and healthcare liability claims (read in the light *least* favorable to the plaintiff) is that the statute of limitations applicable to product liability claims can expire while claims under the Healthcare Liability Act are not yet ripe. Out of an abundance of caution, the Branstetter Actions took a conservative approach and filed claims under the TPLA before the one year anniversary of their injury while waiting for their Healthcare Liability Act claims to ripen. The Branstetter Actions expressly stated they did not contain claims under the THCLA, and many plaintiffs explicitly reserved their right to amend their pleadings to add claims under the THCLA, once such claims became ripe.¹⁰ The plaintiffs then amended their complaints to add claims under the THCLA, and they filed all documents required by the THCLA with their amended complaints.¹¹

As explained above, this Court has already established that this is the proper method of which to handling this procedural catch-22.¹²

c. Under The Plain Language Of The Statute, Plaintiffs Filing Only Products Liability Actions Are Not Required To File A Certificate Of Good Faith Under Tenn. Code Ann. § 29-26-122.

Even if this Court had not already ruled this is the proper method for handling the procedural catch-22 imposed by the competing requirements of the THCLA and the TPLA, the Branstetter Actions still need not comply with the certificate of merit requirements of section 122 for complaints asserting only claims under the TPLA. Put another way, the Specialty Surgery

¹⁰ See e.g., Complaint, Dkt. No. 1, *Savercool v. Ameridose*, Case No.1:13-cv-12583, ¶ 187 (“Out of an abundance of caution, neither this claim, nor any other claim or account asserted in this action, is meant to allege a claim arising under or otherwise covered by the [THCLA]...Plaintiff has served notice letters as required by the [THCLA], but sixty days have not yet passed since service of those letters. Plaintiff files this action to preserve her products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the [THCLA] at the appropriate time. The other Branstetter Actions contain this same paragraph.” ¹¹ See e.g., Amended Complaint, *Savercool v. Ameridose*, Case No. 1:13-cv-12583, Dkt. No. 14.

¹¹ See e.g., Amended Complaint, *Savercool v. Ameridose*, Case No. 1:13-cv-12583, Dkt. No. 14.

¹² Dkt. No. 1360 at P. 20.

Center Defendants are simply wrong in asserting that cases initially asserting only product liability claims must be dismissed for failure to file the certificate of good faith as required by Tenn. Code Ann. § 29-26-122. This position is clearly at odds with the plain language of that statute. In relevant part, Tenn. Code Ann. § 29-26-122 states:

In any health care liability action in which expert testimony is required by § 29-26-115, the plaintiff or plaintiff's counsel shall file a certificate of good faith with the complaint. (emphasis added).

Tenn. Code Ann. § 29-26-115 addresses plaintiff's burden, in a medical malpractice case, of proving a breach of the standard of care in the provision of healthcare services.¹³ Therefore, as is clear from the above-quoted language, a certificate of good faith under Tenn. Code Ann. § 29-26-122 is required if and only if two prerequisites are satisfied: 1) the plaintiff has asserted a claim constituting a "health care liability action"; and 2) the claim requires expert proof related to defendant's breach of the standard of care.

Plaintiffs' claims under the TPLA fail both preconditions: 1) TPLA claims are not "healthcare liability actions" but rather "product liability actions"; and 2) those claims do not require expert testimony as to a breach of the applicable standard of care.¹⁴

It is axiomatic that a claim for strict product liability under the TPLA does not require proof of a breach of the standard of care. The Tennessee Supreme Court has held:

Strict liability in tort is recognized as a cause of action in the TPLA of 1978, Tenn. Code Ann. §§ 29-28-101 to 29-29-108 (1980 and Supp. 1994). Under Tenn. Code Ann. § 29-28-105(a) (1980), a

¹³ In a healthcare liability action, the claimant shall have the burden of proving by evidence as provided by subsection (b): (1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred; (2) That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and (3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred. Tenn. Code Ann. § 29-26-115.

¹⁴ The plaintiffs in the Branstetter Actions make this clear by explicitly disclaiming any liability under the THCLA in their original complaints. See n. 10 *supra*.

manufacturer or seller of a product may be liable for injury to person or property caused by the product if the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller. **Proof of negligence on the part of the manufacturer or seller is not required.**¹⁵ (emphasis added).

The very purpose of strict liability is to relieve the plaintiff of his duty to prove a breach of a duty of care:

We imposed strict liability against the manufacturer and in favor of the user or consumer in order to relieve injured consumers 'from problems of proof inherent in pursuing negligence . . . and warranty . . . remedies . . .' As we have noted, we sought to place the burden of loss on manufacturers rather than injured persons who are powerless to protect themselves.¹⁶

Clearly, claims arising under the TPLA are not claims that “require expert testimony required by Tenn. Code Ann. § 29-26-115.”¹⁷

Moreover, courts in Tennessee routinely hold that plaintiffs asserting claims under the THCLA are not required to file a Section 122 certificate of merit when claims do not require proof of the standard of care. For example, in *Moses v. Dirghangi*, 2013 WL 5519506 (Tenn. Ct. App. Oct. 3, 2013) the Tennessee Court of Appeals held:

The primary consideration in a medical battery case is simply whether the patient knew of and authorized a procedure. This determination does not require the testimony of an expert witness. **Because a medical battery claim does not require expert proof, a plaintiff bringing this claim is not required to file a certificate of good faith pursuant to the [Healthcare Liability Act].**¹⁸

Like medical battery, claims under the TPLA do not require expert proof and a “plaintiff

¹⁵ *Owens v. Truckstops of Am.*, 915 S.W.2d 420 (Tenn. 1996) (emphasis added.)

¹⁶ *Id.* (internal citations and quotations omitted).

¹⁷ Tenn. Code Ann. § 29-26-122.

¹⁸ *Id.* at *11 citing *Hinkle v. Kindred Hosp.*, No. 2012 WL 3799215, at *17, n.11 (Tenn. Ct. App. Aug. 31, 2012 (“Since expert testimony is not required to sustain a claim for medical battery, we concluded that the certificate need not be filed to support such claims.”)).

bringing this claim is not required to file a certificate of good faith pursuant to the [Healthcare Liability Act].¹⁹ Several other cases have come out similarly.²⁰

Accordingly, under the plain language of Section 122, the Branstetter Actions did not need to file a certificate of good faith under Tenn. Code Ann. § 29-26-122 to assert claims under the TPLA.

d. Plaintiffs Have The Absolute Right To Plead Alternative Claims And Amend Their Complaint To Bring Claims In The Alternative.

The Specialty Surgery Center Defendants’ request to dismiss the Branstetter Actions based on the original complaints is wholly without merit. Those original complaints contained product liability claims only, and they were not subject to the requirements of THCLA. However, even assuming *arguendo* that Plaintiffs’ products liability claims could somehow be subject to the certificate of good faith requirements contained in the THCLA, plaintiffs were nevertheless entitled to alternatively plead their products liability claims as falling outside of the scope of the Healthcare Liability Act.²¹

“Under Rule 8(e)(2) of the Federal Rules of Civil Procedure, a plaintiff may plead two or

¹⁹ *Id.*

²⁰ *Truth v. Eskioglu*, 781 F. Supp. 2d 630, 635 n.10 (M.D. Tenn. 2011) (“Even if the [Medical Malpractice] Act required dismissal of the plaintiff’s malpractice claims, at least a portion of her intentional misrepresentation claim would go forward. Regardless of whether a plaintiff has filed a certificate of good faith, the plaintiff’s claims survive to the extent that they do not require expert testimony.”); *Abeyta v. HC Health Servs. of Tenn.*, No. M2011-02254-COA-R3-CV, 2012 WL 5266321 (Tenn. Ct. App. Sept. 18, 2012) (finding that, an involuntary commitment case, the trial court found that all of plaintiff’s claims for medical and negligence *per se* were not medical malpractice claims and that failure to file certificate of good faith did not require dismissal); *Barnett v. Elite Sports Medicine*, No. M2010-00619-COA-R3-CV, 2010 WL 5289669, at *5 (Tenn. Ct. App. 2010) (determining that plaintiff stated a claim for battery, distinct from allegations of medical malpractice, and holding that certificate of good faith was therefore not required because such a claim did not require proof under Tenn. Code Ann. § 29-26-115).

²¹ The Specialty Surgery Center Defendants base this position on the definition of “health care liability action” which “means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, *regardless of the theory of liability on which the action is based.*” Tenn. Code Ann. § 29-26-101(a)(1) (emphasis added). Under the Specialty Surgery Center Defendants’ theory, the language “regardless of the theory of liability” requires that plaintiffs’ asserting claims for personal injury damages against healthcare providers must bring a “health care liability action” and that requirements of Section 121 and 122 apply. Even if that were the case, and based upon the discussion, supra it clearly is not. Under Rule 8(e), plaintiffs would have the right to plead its products liability claims as that term is defined in Tenn. Code Ann. § 29-28-101.

more statements of a claim, even within the same count, regardless of consistency.”²² “The inconsistency may lie either in the statement of the facts or in the legal theories adopted.”²³ In other words, Plaintiffs are entitled under Rule 8 to state a claim under the Products Liability Act and plead that it falls outside of coverage under the Healthcare Liability Act as they did here.

The Specialty Surgery Center Defendants’ position that all claims brought against healthcare providers must be “healthcare liability actions,” and therefore compliance with Section 122 is simply at odds with the alternative pleading rules of Rule 8, which is specifically designed to afford a federal litigant pleading flexibility. As one federal court succinctly stated in the context of an ERISA action:

The reason for employing alternative pleading in cases under the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C § 1001 *et seq.*, is plain enough. Given the uncertainties concerning whether the plan in question is an ERISA plan and the scope of ERISA preemption, it would be foolish to put all of one's eggs in either the ERISA or the state law basket. Fed. R. Civ. P. 8(e)(2) permits such alternative pleading to avoid precisely such dilemmas.²⁴

In other words, under Rule 8, Plaintiffs were not required to place all of their eggs in the “Healthcare Liability Act” basket. They had an absolute right under Rule 8 to alternatively plead claims under the TPLA.²⁵

Furthermore, plaintiffs’ right to plead in the alternative cannot be altered or changed or

²² *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339, 343 (2d Cir. 1994 (“[A] party may properly submit a case on alternative theories.”); *see also Brody v. Stone & Webster, Inc.*, 414 F.3d 187, n. 8 (1st Cir. 2005) (“A plaintiff has the right to plead in the alternative, and the plaintiff’s doing so does not undermine the validity of the complaint.”)

²³ *Id.* citing 2A JAMES W. MOORE & JO D. LUCAS, MOORE’S FEDERAL PRACTICE P 8.32, at 8-214 to 8-215 (2d ed. 1994)

²⁴ *Coleman v. Std. Life Ins. Co.*, 288 F. Supp. 2d 1116, 1121 (E.D. Cal. 2003 quoting *Aiena v. Olsen*, 69 F. Supp.2d 521, 531 (S.D.N.Y. 1999; *see also MacFarlane v. Grasso*, 696 F.2d 217, 224-25 (2d Cir. 1982 (holding that § 1983 plaintiff conceded existence of disputed agency policy only to the extent that he challenged the constitutionality of that policy, but not for purposes of other claims); *Wright v. Olin Corp.*, 697 F.2d 1172, 1184 (4th Cir. 1982 (“It is often appropriate to assess particular Title VII claims and defenses alternatively under different theories.”).

²⁵ *Coleman*, 288 F.Supp. 2d at 1121.

amended by the THCLA, even if the Healthcare Liability Act is considered “substantive” as the Specialty Surgery Center Defendants allege.²⁶ Here, to the extent that the Healthcare Liability Act would prevent a federal litigant from pleading alternative claims of liability, it would not apply to claims brought in federal court.

It is well settled that, when a state substantive law conflicts with a controlling Federal Rule of Civil Procedure, the federal courts must apply the Federal Rule unless that rule exceeds the mandate embodied in the Rules Enabling Act or transgresses constitutional bounds.²⁷ Specifically, the United States Supreme Court held in *Hanna* that:

To hold that a Federal Rule of Civil Procedure must cease to function whenever it alters the mode of enforcing state-created rights would be to disembowel either the Constitution’s grant of power over federal procedure or Congress’ attempt to exercise that power...²⁸

In other words, “when a Federal Rule of Civil Procedure is on point, it, not the state law, governs so long as it does not run afoul of the Rules Enabling Act or the Constitution.”²⁹

The Specialty Surgery Center Defendants’ position that a plaintiff cannot plead claims under the TPLA as existing outside of the THCLA incorrectly urges the same “disemboweling” of the Federal Rule of Civil Procedure that the *Hanna* court rejected by limiting a litigant’s right to plead claims in the alternative. Even if the THCLA prevented Plaintiffs from asserting claims

²⁶ Dkt. No 780, Memo in Support at P. 4 (“The notice and certificate requirements of the [Healthcare Liability Act] are ‘substantive law’ and thus apply in federal court as well.”) (internal citations omitted).

²⁷ *Hanna v. Plumer*, 380 U.S. 460, 463-64, (1965; *see Burlington Northern R. Co. v. Woods*, 480 U.S. 1, 4-5 (1987); *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.*, 559 U.S. 393 (2010; *McCalla v. Royal MacCabees Life Ins. Co.*, 369 F.3d 1128, 1135 (9th Cir. 2004 (“[W]hen a Federal Rule of Civil Procedure is on point, it, not the state law, governs, so long as it does not run afoul of the Rules Enabling Act or the Constitution.”)); *see also Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 611 (4th Cir. 1980 (applying Fed. R. Civ. P. 15(c) rather than contrary North Carolina law regarding relation back of amended pleadings)).

²⁸ *Hanna*, 380 U.S. at 473. *see also Shady Grove*, 130 S. Ct. at 1437 (holding that if a Federal Rule of Civil Procedure “answers the question in dispute...it governs, [state] law notwithstanding-unless it exceeds statutory authorization or Congress's rulemaking power.”).

²⁹ *McCalla*, 369 F.3d at 1135; *see also Piper Aircraft Corp.*, 615 F.2d 606, 611 (4th Cir. 1980); *see also Willever v. United States*, 775 F. Supp. 2d 771, 781 (D. Mary. 2011)(“[W]here a state statute imposes greater procedural burdens on a party than does a Federal Rule of Civil Procedure, and the statute and rule govern the same issue, the state statute cannot be applied in federal court.”).

under the TPLA without first complying with Section 122, the THCLA simply cannot change the right of a federal litigant to plead in the alternative that those products liability claims fall outside of Section 122's requirements.³⁰

As explained above, certain plaintiffs first filed claims under the Product Liability Act to ensure those claims were timely filed under the relevant statute of limitations. They pled those original claims as falling outside of the coverage of the Healthcare Liability Act (i.e. they pled that pre-suit notice and certificate of good faith did not apply to those claims).³¹ Thereafter, once claims under the THCLA ripened, Plaintiffs amended their complaints to assert claims under the Healthcare Liability Act (i.e. medical malpractice) as well as claims under the Products Liability Act (i.e. 'strict products liability'). Because Rule 8(e) allows Plaintiffs to "plead two or more statements of a claim, even within the same count, regardless of consistency,"³² Plaintiffs could plead that their claims under the TPLA existed outside of the THCLA and simultaneously claim certain other claims were subject to the THCLA.³³ That type of alternative pleading is especially appropriate when, as here, Plaintiffs' claims raise complex legal issues that justify raising multiple, inconsistent claims.³⁴

There can be little doubt that Rule 8(e) is a valid federal procedural rule and that it "controls" the issue of whether plaintiffs bringing products liability claims can plead that basis of relief alternatively from any potential claims under the THCLA. Therefore, to the extent that it conflicts with state law, even state substantive law, the federal procedural rule must prevail.³⁵

³⁰ *Henry*, 4 F.3d at 95 ("Under Rule 8(e)(2) of the Federal Rules of Civil Procedure, a plaintiff may plead two or more statements of a claim, even within the same count, regardless of consistency.")

³¹ See e.g., Barger Complaint, at ¶¶ 255- 258; Minor Complaint, at ¶ 172.

³² *Id.*

³³ See *id.* citing *Riverwoods Chappaqua Corp. v. Marine Midland Bank*, 30 F.3d 339, 343 (2d Cir. 1994) ("[A] party may properly submit a case on alternative theories.").

³⁴ See, e.g., *MacFarlane v. Grasso*, 696 F.2d 217, 224-25 (2d Cir. 1982; *Wright v. Olin Corp.*, 697 F.2d 1172, 1184 (4th Cir. 1982; *Coleman*, 288 F. Supp. 2d at 1121.

³⁵ See e.g., *Atlantic Richfield Co. v. Monarch Leasing Co.*, 80 F.3d 204 (6th Cir. 1996; *Piper Aircraft Corp.*, 615

The practical import of this distinction has significant bearing on the Motion. Here, even if the Court were to rule that Plaintiffs' products liability claims as originally pled were subject to the THCLA's certificate of good faith requirements, those claims would not be subject to dismissal because an alternatively pled claim "is not made insufficient by the insufficiency of one or more of the alternative statements."³⁶ In other words, even if Plaintiffs' originally pled products liability claims are subject to dismissal because of failure to satisfy Section 122 requirements, Plaintiffs' amended alternative claims which comply with those statutes survive. Rule 8 compels such a result, and the Healthcare Liability Act cannot change it.

II. The Cain Actions Are Not Subject To Dismissal

For similar reasons as outlined in the above-section, the Cain Actions are not subject to dismissal. Although the Cain Actions did not expressly plead claims in the alternative, the plaintiffs in the Cain Actions amended their complaints and included the certificate of good faith with the amended complaint. Under the *Hanna* and *Shady Grove* principles, they had an ultimate federal right to amend their complaint to cure any procedural or technical defects with the original complaint (assuming any existed to begin with).

Rule 15(a) confers upon a federal litigant the right to amend a pleading once as a matter of course either within 21 days of service of the pleading to be amended or within 21 days after the service of a motion under Rule 12(b).³⁷ Several United States Supreme Court cases dictate

F.2d at 611; *see also Willever*, 775 F. Supp. 2d at 780-81 (refusing to apply state medical malpractice pre-suit expert certification requirements when they conflicted with Rule 26 of the Federal Rules of Civil Procedure).

³⁶ *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 415 F. Supp. 2d 261, 274 (S.D.N.Y. 2005 quoting Fed. R. Civ. P. 8(e)).

³⁷ *See Broyles v. Corr. Med. Servs.*, 478 Fed.Appx. 971 (6th Cir. 2009) (citing *Pertuso v. Ford Motor Credit Co.*, 233 F.3d 417, 421 (6th Cir. 2000) (noting that Rule 15(a) "gives plaintiffs an absolute right to amend their complaint one time before a 'responsive pleading' is served"); *see also Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002)). Here these deadlines were extended and the Court ordered plaintiffs in this case to file amended complaints by December 20, 2013. *See* MDL Order No. 7, Dkt. No. 438.

the applicability of federal procedural rules when those rules conflict with state substantive law.³⁸

In other words, the THCLA cannot limit a federal litigant's right to amend a complaint under Rule 15. Where a state law conflicts with a Federal Rule of Civil Procedure, the federal courts must apply the Federal Rule unless that rule exceeds the mandate embodied in the Rules Enabling Act or transgresses constitutional bounds.³⁹ As explained above, *Hanna* is clear that the Federal Rules of Civil Procedure do not "cease to function whenever it alters the mode of enforcing state created rights."⁴⁰

The Supreme Court's decision in *Shady Grove* is also instructive. *Shady Grove* involved a conflict between Fed. R. Civ. Proc. 23 and N.Y. Civ. Proc. L. § 901(b).⁴¹ New York law precluded class action suits which sought to recover statutory penalties such as statutory interest.⁴² Although the United States Court of Appeals for the Second Circuit held that § 902(b) controlled a federal litigant's right to a class action because it was a substantive rule under the Erie Doctrine, the United States Supreme Court disagreed and held "Rule 23 permits all class actions that meet its requirements, and a State cannot limit that permission by structuring one part of its statute to track Rule 23 and enacting another part that imposes additional requirements."⁴³

In *Shady Grove*, the Supreme Court held that § 901(b)'s application in federal court directly contradicted Rule 23 (which permitted class actions to be filed in all actions) because it

³⁸ *Hanna v. Plumer*, 380 U.S. 460, 463-64, (1965); see *Burlington Northern R. Co. v. Woods*, 480 U.S. 1, 4-5 (1987); *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.*, 559 U.S. 393 (2010); *Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 611 (4th Cir. 1980) (applying Fed. R. Civ. P. 15(c) rather than contrary North Carolina law regarding relation back of amended pleadings).

³⁹ *Hanna v. Plumer*, 380 U.S. at 463-64; *Burlington Northern* 480 U.S. at 4-5.

⁴⁰ 380 U.S. at 473.

⁴¹ *Shady Grove*, 559 U.S. at 397.

⁴² *Id.*

⁴³ *Id.* at 401.

limited the types of claims that could be pursued on a class basis.⁴⁴ Such a result (i.e., a state substantive law trumping a federal procedural right) is impermissible because “the validity of a Federal Rule depends entirely upon whether it regulates procedure...If it does, it is authorized by § 2072 and is valid in all jurisdictions, with respect to all claims, regardless of its incidental effect upon state-created rights.”⁴⁵

“Congress has undoubted power to supplant state law, and undoubted power to prescribe rules for the courts it has created, so long as those rules regulate matters ‘rationally capable of classification’ as procedure.”⁴⁶ As the Supreme Court stated in *Shady Grove*:

What matters is what the [Federal Rule] itself regulates: If it govern[s] only the manner and the means by which the litigants’ rights are enforced, it is valid; if it alters the rules of decision by which [the] court will adjudicate [those] rights, it is not.⁴⁷

In applying this test the Supreme Court noted that it had upheld the application of rules that had “practical effect on the parties’ rights, but each undeniably regulated only the process for enforcing those rights; none altered the rights themselves, the available remedies, or the rules of decision by which the court adjudicated either.”⁴⁸

Hanna is particularly instructive on this point. Supreme Court held that a Massachusetts law requiring in-hand service of process on an executor or administrator of an estate by any putative creditor conflicted with Federal Rule of Civil Procedure 4(d)(1).⁴⁹ After determining that Rule 4(d)(1), which dictated the means of service of a complaint, fell within the limits prescribed by the Rules Enabling Act, the Court concluded that the “clash between Rule 4 and

⁴⁴ *Id.*

⁴⁵ *Id.* (internal citations omitted).

⁴⁶ *Id.* at 406.

⁴⁷ *Id.* at 407 (internal quotations omitted) citing *Mississippi Pub. Corp. V. Murphree*, 326 U.S. 438 (1946).

⁴⁸ *Shady Grove*, at 407-08.

⁴⁹ *Hanna*, 380 U.S. at 470-71.

the Massachusetts law was unavoidable.”⁵⁰ After all, “Rule 4(d)(1) says ‘implicitly, but with unmistakable clarity that [personal] service is not required in federal courts,’ but the Massachusetts law required such personal service.”⁵¹ Because the state law imposed service requirements above and beyond those imposed by a valid, constitutional Federal Rule of Civil Procedure, the Supreme Court held that the state law was in direct collision with the federal law and therefore could not be given effect in the federal courts.⁵²

Rule 15 unequivocally is a federal procedural rule and its liberal amendment policy is regularly used by federal litigants to cure technical deficiencies in a complaint.⁵³ To the extent that Section 122 would operate to prevent and curtail a federal litigant’s right to amend their complaint,⁵⁴ they would be in direct collision with Rule 15’s liberal amendment policy.⁵⁵ Since Rule 15 is undoubtedly a valid procedural rule, Rule 15’s liberal amendment policy controls a

⁵⁰ *Id.* at 470.

⁵¹ *Id.* at 470.

⁵² *Id.* at 470-471.

⁵³ See *Piper Aircraft*, 615 F.2d at 610-11 (applying Fed. R. Civ. P. 15(c) because it governed a procedural right and was directly contradicted by a North Carolina law regarding relation back of amended pleadings); see, e.g., *Tefft v. Seward*, 689 F.2d 637 at 638-39 (overturning denial of motion to amend to cure technical pleading defects where on the face of the original complaint, plaintiff clearly sought to assert an action for tort and other claims); *Berkshire Fashions v. M.V. Hakusan II*, 954 F.2d 874, 886-88 (3d Cir. 1992) (allowing plaintiff to amend under Rule 15(a) to drop a non-diverse party in order to preserve jurisdiction); *Stanley v. Central Intelligence Agency*, 639 F.2d 1146, 1159-60 (5th Cir. 1981) (granting leave to amend when it appeared that plaintiff may have pleaded a colorable section 1983 claim in his complaint, rather than the Federal Tort Claims Act cause of action asserted); *May Dep’t Store v. Graphic Process Co.*, 637 F.2d 1211, 1216 (9th Cir. 1980) (reaching same result as *United Steelworkers*); *United Steelworkers of Am. v. Mesker Bros. Indus., Inc.*, 457 F.2d 91 (8th Cir. 1972) (allowing plaintiff to amend to refashion federal claim that was improperly pled); *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563 (S.D. Tex.) (permitting party to file amended complaint to cure technical defects as they related to the court’s subject matter jurisdiction).

⁵⁴ At least one Tennessee Court of Appeals decision addresses this issue and suggests that Section 122 in fact curtails a state litigant’s rights to use Tenn. R. Civ. P. 15’s liberal amendment policy to cure Section 122 deficiencies. *Vaughn v. Mountain States Health All.*, 2013 WL 817032 (Tenn. Ct. App. Mar. 5, 2013). But the issue is different in federal court where the Tennessee legislature cannot pass an act that would curtail a federal litigant’s rights under the Federal Rules of Civil Procedure.

⁵⁵ See *Hanna*, 380 U.S. at 471 (“When a situation is covered by one of the Federal Rules, the question facing the court is a far cry from the typical, relatively unguided *Erie* choice: the court has been instructed to apply the Federal Rule, and can refuse to do so only if the Advisory Committee, this Court, and Congress erred in their *prima facie* judgment that the Rule in question transgresses neither the terms of the Enabling Act nor constitutional restrictions.”).

federal litigants' rights to amend their complaint to cure any technical non-compliance with Tenn. Code Ann. 29-26-122.⁵⁶

Accordingly, the Cain Actions are not subject to dismissal because their amended complaint is the operative complaint and it complies with Section 122. The Specialty Surgery Center Defendant's claims that the Cain Actions are subject to dismissal because their original complaints are defective are therefore without merit.⁵⁷

III. The Remaining Actions Should Be Permitted An Extension To File A Certificate Of Good Faith

a. In The Fall Of 2013, It Remained Unclear Whether Cases Such As The One At Bar Were Product Liability Actions Or Healthcare Liability Actions

As the Court has become all too aware, there is significant overlap in the coverage of the TPLA and the THCLA. The TPLA, codified at Tenn. Code Ann. § 29-28-101, *et seq.*, expressly authorizes claims for strict tort liability against sellers of defective or unreasonably dangerous products in certain limited circumstances, including when a product manufacturer is judicially declared insolvent.⁵⁸ The primary purpose of providing for seller liability "is to insure that where the manufacturer is insolvent, an injured party may look to a solvent seller for his losses."⁵⁹

The statute sets forth the grounds for a strict liability cause of action against a "seller" or "distributor" of a product, and defines those terms broadly. A "[s]eller includes a retailer, wholesaler, **or distributor**, and means **any individual or entity engaged in the business of**

⁵⁶ See *Id.*; see also *Piper Aircraft*, 615 F.2d at 610-11.

⁵⁷ *Hanna*, 380 U.S. at 473 ("To hold that a Federal Rule of Civil Procedure must cease to function whenever it alters the mode of enforcing state-created rights would be to disembowel either the United States Constitution's grant of power over federal procedure or Congress' attempt to exercise that power in the Rules Enabling Act, 28 U.S.C.S. § 2072."); see also *Atlantic Richfield Co. v. Monarch Leasing*, 84 F.3d 204 at 207 ("Under the Court's holding in *Hanna*, we must follow [Rule 58] unless we find that it is invalid under the Rules Enabling Act, 28 U.S.C. § 2072, or the Constitution, which we do not.").

⁵⁸ Tenn. Code Ann. § 29-28-106(5).

⁵⁹ *Seals v. Sears, Roebuck and Co., Inc.*, 688 F. Supp. 1252, 1256 (E. D. Tenn. 1988).

selling a product, whether such a sale is **for resale**, or **for use** or **consumption**.”⁶⁰ This provision does not contain any qualifying language before the phrase “entity engaged in the business of selling of a product.” A “product” means “any tangible object or goods produced.”⁶¹ There is no dispute that the MPA at issue was a “product” under the TPLA.

The TPLA also defines a “product liability action” broadly:

“Product liability action” for purposes of this chapter **includes all actions** brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. “Product liability action” includes, **but is not limited to, all actions** based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or **under any other substantive theory in tort or contract whatsoever**.⁶²

Additionally, Section 103(c) of the PLA sets forth an extended statute of repose for actions against manufacturers or sellers of silicone breast implants.⁶³ The statute then carves out healthcare providers from the definition of the term “seller” for purposes of breast implant litigation only. Specifically, in relevant part, Section 103(c) provides:

(c)(2) *For purposes of this subsection (c) only*, “seller” does not include a hospital or other medical facility where the procedure took place, nor does “seller” include the physician or other medical personnel involved in the procedure.⁶⁴

Taken together, the broad definition of a healthcare liability act and the statutory carve out specifically exempting healthcare providers from coverage make it unclear whether claims in this litigation can or should be construed as falling under the TPLA or the THCLA.⁶⁵

⁶⁰ Tenn. Code Ann. § 29-28-102(7) (emphases added).

⁶¹ Tenn. Code Ann. § 29-28-102(5).

⁶² Tenn. Code Ann. § 29-28-102(6) (emphases added); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013).

⁶³ Tenn. Code Ann. § 29-28-103(c)(1).

⁶⁴ Tenn. Code Ann. § 29-28-103(c)(emphasis added).

⁶⁵ A well-established rule of statutory construction is “the maxim ‘*expressio unius est exclusio alterius*,’ which states

On the other hand, the HCLA defines a “health care liability action” as “any civil action . . . alleging that a health care provider or providers have caused an injury **related to the provision of**, or failure to provide, **health care services to a person**, regardless of the theory of liability on which the action is based.”⁶⁶ The statute states that “health care services to persons” includes “care by health care providers which includes care by physicians, nurses, licensed practical nurses, pharmacists, . . . and other agents, employees, and representatives of the provider . . .”⁶⁷ The Act states that “any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint[.]”

Despite this broad definition, several Tennessee courts have found that claims against healthcare providers do not always allege claims under the THCLA.⁶⁸ In other words, simply because the Remaining Actions sought relief against a healthcare provider for a personal injury did not necessarily mean that those claims were claims under the THCLA because the injury involved in this case stems from plaintiffs exposure to a dangerous product that would in any other context fall squarely within the broad definition of a product liability action under the TPLA.

the principle that the expression of one thing implies the exclusion of all things not expressly mentioned.” *Limbaugh v. Coffee Med. Ctr.*, 59 S.W.3d 73, 84 (Tenn. 2001). According to the Tennessee Supreme Court, “the mention of one subject in a statute means the exclusion of other subjects that are not mentioned. Omissions are significant when statutes are express in certain categories but not others.” *Carver v. Citizen Utilities Co.*, 954 S.W.2d 34, 35 (Tenn. 1997) (citations omitted).

⁶⁶ Tenn. Code Ann. § 29-26-101(a)(1) (emphases added).

⁶⁷ Tenn. Code Ann. § 29-26-101(b).

⁶⁸ *Malott v. Marriott Hotel Servs.*, 2016 WL 4191727 (M.D. Tenn. August 9, 2016); *Parker v. Portland Nursing & Nursing Rehab*, 2012 WL 3776800, *11 (Tenn. Ct. App. Aug. 30, 2012) (refusing to dismiss claims not covered by the THCLA); *see also Fleming v. Saini*, 2014 WL 2592548, at *5 n.7 (Tenn. Ct. App. June 10, 2014) (“Trial courts should be vigilant to guard against misuse of the TMMA as a vehicle for a defendant to obtain dismissal of a lawsuit that is not primarily a health care liability action.”).

After several rounds of briefing, this Court ultimately concluded that claims must proceed strictly under the THCLA, not the TPLA.⁶⁹ Prior to that court ruling, no Court had ever attempted to determine the implications of the broad coverage of the TPLA and the THCLA.⁷⁰

b. Section 122 Does Not Require Automatic Dismissal Of Complaints That Fail To Comply With Section 122

The Tennessee Court of Appeals has held that “the plaintiff’s failure to timely file a ‘certificate of good faith...’ is not always fatal to the plaintiff’s claim. Instead, upon a showing of good cause, the plaintiff may obtain an extension within which to file a certificate of good faith.”⁷¹ Accordingly, under Tennessee law, “a trial court may grant an extension for filing a certificate of good faith, even after the expiration of the time period in which the act was to be completed.”⁷²

Here, the broad definitions of the TPLA and the THCLA create conflicting requirements and Plaintiffs’ counsel are not meant to be clairvoyant in interpreting statutes without court guidance. Any failure to timely file a certificate of good faith, therefore, is principally due to the law’s lack of clarity as to whether claims involving a doctor that sells a dangerous product that ultimately injures a patient are required to proceed under the procedural requirements of the TPLA or the THCLA.

Fortunately, the Tennessee state legislature provided clearly defined language to prevent unfairness in cases where misinterpreting this question initially, not prove fatal to Plaintiff’s claims. Especially when the spirit of Section 122’s requirements are clearly not met in this

⁶⁹ Dkt. Nos. 2700 and 3027.

⁷⁰ *See id.*

⁷¹ *Stovall v. UHS of Lakeside, LLC*, 2014 WL 2155345, *27 (Tenn. Ct. App. Apr. 22, 2014) overruled on other grounds at *Davis v. Ibach*, 465 S.W.3d 570 (Tenn. 2015).

⁷² *Id.*

instance. The purpose of Section 122 is to root out frivolous claims that have no merit.⁷³ Here, 17 other cases have provided certificates directly addressing the merits of plaintiffs' claims against Specialty Surgery Center. The Remaining Actions ultimately decided to proceed along a different path working under a different understanding of the interactions between the TPLA and the THCLA. They should not be punished for getting the question wrong, and accordingly should be permitted an extension on filing the Section 122 certificates.⁷⁴

CONCLUSION

Based upon the forgoing reasons, the Specialty Surgery Center Defendants' Motion to Dismiss should be denied because the Motion itself lacks merit, or, in the alternative, should the court find Defendants' Motion with merit, those Plaintiffs' should be permitted an extension of time to file the certificate of good faith, because clearly Plaintiffs' claims are not frivolous and have merit.

Dated: October 7, 2016

Respectfully submitted,

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⁷³ *Jenkins v. Marvel*, 683 F. Supp. 2d 626, 639 (E.D. Tenn. 2010) "[O]ne of the other important purposes of [Section 122] was to dispose of frivolous suits before any party incurred substantial litigation expenses."

⁷⁴ *Stovall* 2014 WL 2155345, *27 (granting a motion to extend the time for filing a certificate of good faith even after the filing of a motion to dismiss where plaintiff's counsel misinterpreted the requirements of Section 122 and showed good cause for an extension). Accordingly, the PSC contemporaneously files a cross motion to extend the time for filing the Section 122 certificates for all cases subject to the Motion.

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CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 7, 2016

/s/ Benjamin A. Gastel
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